PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P715PC00		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK 03/00533	11.08.2003	12.08.2002
International Patent Classification (IPC) or both national classification and IPC		
A61M1/00		
Applicant		
TRACECOMPANY HOLDING APS et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
12.03.2004	12.11.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Pille, S Telephone No. +49 89 2399-2097

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK 03/00533

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-48 filed with telefax on 09.11.2004

Drawings, Sheets

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 37-48

   because:

   ☒ the said international application, or the said claims Nos. 37-48 relate to the following subject matter which does not require an international preliminary examination (specify):

   see separate sheet

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-36
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-36
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	

2. Citations and explanations

see separate sheet

ad III

1). For the assessment of the present claims 37-48 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims.

Claims 37-48 relate to subject-matter considered by this Authority to be covered by the provisions of R. 67.1(iv) PCT: methods of treatment of the animal body by therapy (e.g. administration of medicaments to an animal, conferring passive immunity to a calf). Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

ad V

2). The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claim 1 is not new over US5188610. This document shows a device for oral administration of a fluid source to an animal (col. 1, l. 6-11 and 55-56) comprising features:
I) col. 4, l. 32-36
ii) fig. 1 (82)
iii) fig. 1 (80)
iv) fig. 1 (72)
    a) fig. 3 (78)
    b) fig. 3 (40)
v) claim 10 c.
The subject-matter of claim 1 is therefore new. The differentiating features cannot be found in the remaining cited documents. The problem solved by these features is the provision of a simple and inexpensive bag which is protected by the container against penetration by sharp objects. It follows that the subject-matter of claim 1 is inventive.

3). Claim 2-34 are dependent on claim 1 and claims 35-36 use the device according to claims 1-34. As such they also meet the requirements of the PCT with respect to novelty and inventive step.

Claims

1. A portable device for oral administration of a fluid source to an animal, said device comprising

i) a hollow, axially-elongated member comprising
   a) a distal end comprising a first opening, preferably in the form of a nozzle portion, and
   b) a proximal end comprising a second opening connected to

ii) a handle comprising
   a) a distal portion connecting the handle to said axially-elongated member, and
   b) a proximal portion connecting the handle to

iii) a flexible tube comprising

   a) a distal end comprising a first opening connected to the handle, and
   b) a proximal end comprising a second opening connected to

iv) a hollow adaptor capable of attaching the flexible tube to a fluid source container, said adaptor comprising
   a) a distal end comprising a first opening, said distal end capable of securing attachment of said adaptor to the tubing, and
   b) a proximal end comprising a second opening, said proximal end capable of bringing the adaptor in contact with the fluid source stored in

v) said device further comprising a switch mechanism for regulating the flow of liquid through the axially-elongated member,

wherein the fluid source of the device is stored in a container insert in the form of a disposable, flexible polymer bag, said

container insert being arranged in the fluid source container fitted to holding said container insert, said fluid source container comprising

a) at least one attachment site capable of securing the attachment of the container to the adaptor, and

b) means for transporting the device by the operator.

2. The device according to any of the preceding claims, wherein the axially-elongated member comprising the nozzle portion is capable of being inserted into the esophagus of a domestic animal.

3. The device according to any of the preceding claims, wherein the nozzle is rounded in shape and has an outer diameter larger than the outer diameter of the rest of the axially-elongated member.

4. The device according to any of claims 2 and 3, wherein the nozzle portion is of a shape and size which preferably inhibits the axially-elongated member from being inserted into the trachea of the domestic animal.

5. The device according to any of claims 3 to 5, wherein said axially-elongated member and said nozzle portion is manufactured as integrated into one piece of material.

6. The device according any of the preceding claims, wherein the axially-elongated member has retained at least some degree of flexibility.

7. The device according to any of claims 1 to 5, wherein the axially-elongated member is essentially inflexible.

8. The device according to any of the preceding claims, wherein the axially-elongated member comprises or consists of a polymer.

9. The device according to claim 8, wherein the polymer is a thermoplastic polymer.

10. The device according to claim 9, wherein the polymer is polypropylene or polyethylene.

11. The device according to any of the preceding claims, wherein the length of the axially-elongated member from the tip of the nozzle portion to the distal portion of the handle is from 30 cm to 34 cm, such as about 32 cm.

12. The device according to any of the preceding claims, wherein the inner diameter of the axially-elongated member excluding the nozzle portion is from 0.5 cm to 2 cm, such as about 0.8 cm, for example about 1.0 cm, such as about 1.2 cm, for example 1.5 cm.

13. The device according to claim 12, wherein the outer diameter of the axially-elongated member excluding the nozzle portion is from 0.2 cm to about 1 cm larger than the inner diameter of the rest of the axially-elongated member.

14. The device according to any of the preceding claims, wherein the switch mechanism for regulating the flow of fluid source through the axially-elongated member is comprised in the handle.

15. The device according to claim 14, wherein the switch mechanism is manually operated.

16. The device according to any of the preceding claims, wherein the switch mechanism comprises a valve.

17. The device according to any of the preceding claims, wherein the switch mechanism comprise a sliding valve.

18. The device according to any of the preceding claims, wherein the shape and size of the handle prevents it from being inserted into the mouth of the animal thereby preventing the axially-elongated member from reaching beyond a predetermined region of the esophagus.

19. The device according to any of the preceding claims, wherein the handle is hollow.

20. The device according to any of the preceding claims, wherein the handle is detachably connected to the axially-elongated member.

21. The device according to any of the preceding claims, wherein the handle consists of at least two detachable parts.

22. The device according to any of the preceding claims, wherein the adaptor comprises a tapering end.

23. The device according to claim 22, wherein the tapering end is capable of penetrating said container insert.

24. The device according to claim 23, wherein said adaptor further comprises a shoulder distal to said tapering end for providing a tight connection between the adaptor and said container insert.

25. The device according to any of claims 22 to 24, wherein said adaptor further comprises a plurality of locking pins for securing the attachment of the adaptor to said fluid source container.

26. The device according to any of claims 22 to 25, wherein said adaptor further comprises two oppositely located planar flanges for rotating the adaptor into locking position once it has made contact with the fluid source container.

27. The device according to any of the preceding claims, wherein said adaptor further comprises a portion for detachably connecting the adaptor to a cleaning device.

28. The device according to claim 27, wherein said cleaning device is a water tap optionally fitted with a hosepipe adaptor capable of detachably connecting the water tap to the adaptor of the device.

29. The device according to claims 1, wherein said container further comprises means for engagement of said adaptor on the inside of said at least one attachment site.

30. The device according to any of claims 1 to 29, wherein said container further comprises one or more means for transporting the device by the operator.

31. The device according to claim 30, wherein said means for transporting enable the operator to carry the container on his back.

32. The device according to any of claims 1 to 32, wherein the container comprises a single polymer sheet capable of folding into a container, said polymer sheet comprising

a first wall portion, a second wall portion, and a base portion

wherein the first wall portion is permanently fixed to said second wall portion along a single first axis,

wherein said first wall portion is permanently fixed to a base portion along a single second axis,

wherein said second wall portion is detachably fixed to said first wall portion along a single third axis,

and wherein said second axis connects said first and third axes.

33. The device according to any of claims 1 to 32, wherein said container is capable of being unfolded into an essentially planar sheet when not in use.

34. The device according to any of claims 1 to 33, wherein the container insert is disposable.

35. A method for oral administration of a fluid or liquid source to an animal, said method comprising the steps of

i) providing a fluid or liquid source,

ii) providing a device according to any of the previous claims

iii) filling said container insert of the device with said fluid or liquid source, and

iv) administering said fluid or liquid source to said animal, optionally by operating said switch mechanism.

36. The method according to claim 35, wherein said device is according to any of claims 1 to 34.

37. The method according to claim 36, wherein the liquid source is selected from the group consisting of colostrum, aqueous solutions of nutrients or electrolytes, aqueous solutions of medicaments and the like.

38. The method according to claim 37, wherein the liquid source is colostrum.

39. The method according to claim 38, wherein the colostrum is obtained from a domestic animal, including a bovine species.

40. The method according to claim 39, wherein the domestic animal is a ruminant.

41. The method according to claim 40, wherein the ruminant is a bovine species.

42. The method according to claim 41, wherein the bovine species is selected from the group consisting of Holstein and Jersey.

43. The method according to any of claims 41 or 42, wherein the bovine species is a newly born bovine species less than twenty days old.

44. The method according to claim 43, wherein the bovine species is a newly born bovine species less than fifteen days old.

45. The method according to claim 44, wherein the bovine species is a newly born bovine species less than ten days old.

46. The method according to claim 45, wherein the bovine species is a newborn bovine species less than five days old.

47. A method for conferring passive immunity to a newly born domestic animal, said method comprising the steps of

i) providing a passive immunity source, such as immunoglobulins,

ii) providing a device according to any of claims 1 to 34,

iii) filling said container insert of the device with said passive immunity source, and

iv) administering said passive immunity source to said bovine species, optionally by operating said switch mechanism.

48. The method of any of claims 36 to 47, wherein the device used is according to any of claims 1 to 34, and wherein the size of the nozzle allows the operator of the device to determine the present position of the nozzle in the esophagus from the outside of the animal by pressing said nozzle portion against the inside wall of the esophagus.